Volumetric Correction of the Aging Face with Poly-L-Lactic Acid

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Disclosures

- Sanofi-Aventis

- Sculptra National Injection Trainer

- Sculptra National Speaker’s Bureau

- This lecture does not qualify as an official training!
Extrinsic vs. Intrinsic Aging
Sinking or Sagging?
The Fat Compartments of the Face: Anatomy and Clinical Implications for Cosmetic Surgery


Clinical observation and laboratory investigations suggest that the subcutaneous fat of the face exists in distinct anatomical compartments (Fig. 5). When the operating surgeon performs a face lift, areas of subcutaneous fat are encountered that alternate with areas where no fat is present. The natural fat is a discrete unit with distinct anatomical boundaries. Fat, when present, is composed of three compartments: subcutaneous, medial, and lateral. Individual fat compartments develop primarily through the following mechanisms: lost of body fat, growth or decline in size of subcutaneous fat, and aging of skin and subcutaneous fat. Fat compartments are located predominantly in the subcutaneous fat, with a smaller amount in the superficial fat. Fat compartments are related to the size of the skin and subcutaneous fat, and they are not moved by the skin. Fat compartments are related to the size of the skin and subcutaneous fat, and they are not moved by the skin. Fat compartments are related to the size of the skin and subcutaneous fat, and they are not moved by the skin. Fat compartments are related to the size of the skin and subcutaneous fat, and they are not moved by the skin.

MATERIALS AND METHODS

Thirteen facial and neck fat compartments were performed on 13 male and 13 female patients, ranging in age from 47 to 82 years. Preoperative studies included multiple techniques to determine the best diverging techniques. Lebaron. Bodhi Fat tech, and metathese block were all evalu-
Fat Compartments of the Face

Malar Fat Pads

- Nasal-Labial & Medial
- Middle
- Lateral Temporal-Cheek
Fat Compartments of the Face

Submentalis Fat Pad
There are distinct superficial and deep fat compartments

- Unable to flow past their respective septal boundaries i.e. retaining ligaments

- Fat compartments age independently

- Volume loss in one area causes folds in adjacent areas = “Pseudoptosis” or Domino effect

There have been many ideas on how aging occurs. An overall effect of aging is the laxity of skin. The face is made up of the forehead, the cheeks, and the mandible. The forehead is made up of the glabellar region, the areas above the eyebrows, and the frontalis muscle. The cheeks are divided into the malar and zygomatic regions. The mandible is made up of the submandibular and submental regions. The submandibular region is characterized by the muscles of the lower lip and the submandibular gland. The submental region is characterized by the muscles of the lower neck and the submental fat pad.

Medial

Middle
Deflation vs. Descent\textsuperscript{1}
Bone Loss plays significant role in aging process:
- Alveolar Bone Loss
- Flattening of Malar Eminence
- Increased Pyriform Aperture
- Orbital Rim Loss
- Clockwise Rotation of Midface
# Treatment options

<table>
<thead>
<tr>
<th>Type</th>
<th>Product(s)</th>
<th>FDA-Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxins</strong></td>
<td>Botox® Cosmetic (Botulinum Toxin Type A)</td>
<td>4/12/2002</td>
</tr>
<tr>
<td><strong>Traditional fillers</strong></td>
<td>Colloids&lt;br&gt;CosmoDerm®/CosmoPlast® (Human-based Collagen Implant)&lt;br&gt;Evolence® (Collagen Filler)</td>
<td>3/11/2003&lt;br&gt;6/27/2008</td>
</tr>
<tr>
<td><strong>Hyaluronic acids</strong></td>
<td>Restylane® (Hyaluronic Acid Gel)&lt;br&gt;Juvéderm® (Hyaluronic Acid Gel)&lt;br&gt;Perlane® (Hyaluronic Acid Gel)&lt;br&gt;Elevess™ (Hyaluronic Acid With Lidocaine)</td>
<td>12/12/2003&lt;br&gt;6/2/2006&lt;br&gt;5/2/2007&lt;br&gt;7/24/2007</td>
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<tr>
<td><strong>Collagen replacers</strong></td>
<td>Radiesse® (Calcium Hydroxylapatite Gel)&lt;br&gt;Sculptra®Aesthetic (poly-L-lactic acid)</td>
<td>12/22/2006&lt;br&gt;7/28/2009</td>
</tr>
<tr>
<td><strong>Permanent fillers</strong></td>
<td>Artefill® (Polymethylmethacrylate Implant)</td>
<td>10/27/2006</td>
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</table>

Botox is a registered trademark of Allergan Inc. Cosmoderm and CosmoPlast are registered trademarks of Inamed. Evolence is a registered trademark of ColBar LifeScience Ltd. Restylane and Perlane are registered trademarks of HA North American Sales AB, a subsidiary of Medicis Pharmaceutical Corporation. Juvéderm is a registered trademark of Allergan Industrie SAS. Elevess is a trademark of Anika Therapeutics. Radiesse is a registered trademark of BioForm Medical, Inc. Artefill is a registered trademark of Artes Medical, Inc.
# Fat vs. Sculptra

<table>
<thead>
<tr>
<th>Fat</th>
<th>Sculptra</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative Procedure</td>
<td>In Office</td>
</tr>
<tr>
<td>Down time/edema</td>
<td>No down time</td>
</tr>
<tr>
<td>Steeper Learning Curve</td>
<td>Different, not Difficult</td>
</tr>
<tr>
<td>Unpredictable Absorption</td>
<td>Predictable growth</td>
</tr>
<tr>
<td>Sudden Change</td>
<td>Subtle progressive change</td>
</tr>
<tr>
<td>$$$ (Equipment/OR)</td>
<td>$ -$$$ (Product)</td>
</tr>
</tbody>
</table>
Where Do You Place Sculptra Aesthetic Versus Other Products?

- **Neuro Modulator**
- **Filler**
- **Sculptra Aesthetic**
Sculptra – What Is It?

- Poly – L – Lactic Acid
- By-product of Sugar Fermentation
  - 40 - 60 Micron Particles
  - Irregularly Shaped
  - “Spikey” i.e. sharp edges under scanning EM
Sculptra-How Does It Work?

- Macrophage Foreign Body Response
  - Particle Size
  - Particle Shape

- Stretch Effect on Fibroblasts

- Type I Collagen Formation over subsequent 6 weeks
Presentation of PLLA

- Non-refrigerated
- Formulated as a lyophilized powder
- Sculptra contains:
  - Crystalline Powder Form of Poly-L-lactic acid
  - Mannitol
  - Sodium Carboxymethylcellulose
Reconstitution of PLLA

- Add slowly
  - 4.5 cc 2% Lidocaine Plain
  - 4.5 cc Bacteriostatic Water
  - > 8 cc Dilution!

- Avoid Foam

- Allow to sit – Hydrophobic !!
  - Minimum of 48 hours
  - Room Temperature
Patient Identification

?Sinking or Sagging?

Identify/Isolate areas of volume loss
Patient Consultation

- Isolate/Identify areas of volume loss
  - [ ]
- Discuss properties of PLLA
  - [ ] Non‐Allergenic
  - [ ] Natural
  - [ ] Made in muscle
  - [ ] Used in absorbable suture
  - [ ] Breaks down to carbon dioxide & water
  - [ ] Completely gone in 12‐18 months
Patient Consultation

- Abrupt/Discrete changes between fat compartments plays a prominent role in the aging process
Patient Consultation

• Discuss properties of PLLA (continued)

  ➢ Final result is from new collagen, not the product
  ➢ Is a BIOSTIMULATOR, not a filler

• Results are gradual – Very Important to set expectations
  ✓ Creating sheets/layers of collagen
  ✓ Use analogy of “seeds” of collagen
  ✓ May not see much from first session – creating a scaffold
Patient Consultation

• Results are:
  
  • Gradual
    • Set Expectations!!
  
  • Natural
    • Native Collagen – feels soft/natural, not stiff (e.g. Radiesse)

• Longlasting i.e. > 2years
  
  • Exceptions
    • Inherently thin
    • “Gym Rats”
    • Poor Skin Tone
In a survey of 383 women, consumers prefer gradual results lasting 2 years

Survey question: Which statement is more important to you in your decision to have a physician-administered treatment for lines, wrinkles, or folds—gradual results that last 2 years or immediate results that last 1 year?*

* From a 2008 joint American Society for Dermatologic Surgery (ASDS) and sanofi-aventis U.S. survey of consumer attitudes on nonsurgical cosmetic procedures for the face, conducted with 383 women aged 35-69 who are considering medical anti-aging treatment within the next 2 years.

Ultrasound Response

Valantin et al. *AIDS*. 2003,17:2471
Contraindications

- Connective Tissue Disorders e.g. Lupus, Scleroderma
- H/O Sarcoidosis
- H/O Keloid Formation
- Allergy to components
  - PLLA
  - Mannitol
  - Sodium Carboxymethylcellulose
Risks

- **Nodules (> 5mm)**

- **Papules (< 5mm)**
  - Both < 1% with proper technique
  - Palpable, usually not visible
Granuloma vs. Nodule/Papule

- Granulomas are a rare event with an incidence < 1% reported with virtually every commercially available injectable
  - Precipitating Factors are still poorly understood

- Nodules/Papules are now realized to be predictable and preventable AE’s that have decreased dramatically with evolving methodology
Aesthetic Surg 2003;23:221-224

J Oral Pathol Med 2004;33:115-120


Dermatology 2006;213:300-304


British J Plas Sur 2007;04.002:1079-1080
Injection Technique

- Contraindicated injection sites:
  - Periorbital
    i.e. Orbicularis Oculi
  - Vermillion/Lip
  - Modiolus
  - Depressor Anguli Oris Tendon

- Are “Hyperkinetic Muscles
- Sweeps/Consolidates PLLA causing nodules
Evolving Methodology has Significantly Lowered Rate of Adverse Events

Incidences of Papules in Clinical Studies of Sculptra®: 52%, 31%, 13%, 6%, 8.6%, 1%, 3%, 1%, 2.3%.

- Blue Pacific, N=99, US 2002
- APEX 002, N=99, US 2002
- SoC Cosmetic FDA, N=204, US 2002
- U.S. Market, N=204, FDA 2005
- EU Market, N=300, MPA 2004
- APEX 002, N=99, US 2002
- St. Biologiques, N=2700, France 2007
- APEX 002, N=204, US 2002
- APEX 002, N=99, US 2002
What has changed?

- Increased Dilution – minimum of 8 cc
- Increased Hydration Time – minimum of 48 hours
- Increased Time Frame Between Injections
- Injection Technique
  - Dermal-Subcutaneous Junction, NOT Intradermal
  - Supraperiosteal whenever possible
What has changed?

- Injection Technique
  - Dermal-Subcutaneous Junction, NOT Intradermal
  - Supraperiosteal whenever possible
Like the glabellar region, the nasal ala may be a particular region in which blood supply depends strongly on a single arterial branch.
Sculptra® Aesthetic (injectable poly-L-lactic acid)
A commitment to core specialists

Committed only to Dermatologists and Plastic Surgeons

- We train board-certified Dermatologists, Plastic Surgeons, and Facial Plastic Surgeons on Sculptra® Aesthetic
- We only sell Sculptra® Aesthetic to Sculptra®-trained physicians
- We provide an industry-recognized physician training program
  - In-office training with a facial rejuvenation Key Thought Leader
  - Complete training kits for patient practice
- Dermik is committed to building patient demand for Sculptra® Aesthetic with trained and experienced physicians

The Sculptra® training program was the only training program to receive a 2007 American Society for Dermatologic Surgery Dermasurgery Diamond Award.

Please see full Prescribing Information available at this presentation.
Two Year Post Injection Results

61 yo s/p 1 vial/session X 4 sessions

T. Hamilton, M.D.
Two Year Post Injection Results

50 y/o s/p ½ vial/session X 2 sessions

B. Robinson, M.D., F.A.C.S.
Patient Consultation

Photos courtesy of Rhonda Baldone MD
Two Year Post Injection Result

55 yo s/p 1 vial/session X 3 sessions

B. Robinson, M.D., F.A.C.S.
Two Year Post Injection Result

55 yr s/p 1/2 vial/session X 2 sessions

B. Robinson, M.D., F.A.C.S.
Global vs Local Facial Shape and Proportions

PLLA 1-2 vials/session, 5 vials total/ 4 sessions total over 18 months
Two Year Post Injection Result

40 yo s/p 2 vial/session X 3 sessions

B. Robinson, M.D., F.A.C.S.
AAFPRS 2009 Survey

- ...patients “opting to have less invasive procedures”...
- “The economy is playing a large role in the growing trend.”
- "We are excited to see patients making educated choices.” Dr. Rousso
- the greatest increase being poly-l-lactic acid (up 71 percent).
If not now, then when?
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